IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Sven Schreder et al. Group Art Unit: 1614

Serial No.: 10/661,588 Examiner: Phyllis G Spivack

Filed: September 15, 2003

For: Pharmaceutical Preparation

DECLARATION UNDER 37 C.F.R. § 1.132

Honorable Commissionar of
Patents and Trademarks
Washington, D.C. 20231

SIR:

Hiltrud Lindenblatt, being duly warned, deposes and says:

I am a citizen of Germany;

I am a pharmacist by training and experience;

the degree of D. Rer. Nat.. was bestowed on me by the Eberhard-Karls-University of Tübingen , Germany in 1998;

since October 1998 I have been with Merck KGaA, Darmstadt;

since November 2000 I´ve been in charge of the Pharmaceutical Development Department of Merck KGaA, Darmstadt, Germany; and since then I´ve got responsibility on formulation development of Merck KGaA.

The test results presented below for the present application prove that the claimed pharmaceutical preparation has an improved storage stability compared to the preparations known in the art.

I have carried out, or supervised experiments for preparation and stability testing of pharmaceutical preparations according to the methods described within the genus claimed in the pending application.

Experimental Report

Compositions and Preparation of Formulations used for Stability Testing

Ingredients	Formulation A	Formulation B	Formulation C
Levothyroxine Sodium	0.105 mg	0.105 mg	0.105 mg
Lactose monohydrate	67.40 mg	68.40 mg	60.90 mg
Maize starch	25.00 mg	25.00 mg	25.00 mg
Gelatin		2.50 mg	10.00 mg
HPMC	3.50 mg		
Croscarmellose Sodium	3.50 mg	3.50 mg	3.50 mg
Magnesium Stearate	0.50 mg	0.50 mg	0.50 mg

The compositions of formulations A, B and C were processed to tablets as described in Example 1 of the present application.

Stability testing

The content of undesired degradation products in each formulation were measured before and after storage at 25°C / 60 % r.H. using a reversed phase HPLC method and UV detection. The results obtained are presented in the following table:

	Levothyroxine Sodium Degradation Products in % (w/w)		
Storage time	Formulation A	Formulation B	Formulation C
0 (before storage)	2.09	0.49	0.68
104 weeks	8.84	4.34	3.54

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such wilful false statements may jeopardize the validity of the application or any patent issuing thereon.

7.2.08
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Date

Hiltrud Lindenblatt